

Position Summary:

Under general supervision of the Laboratory Director, this position serves as a key policy advisor and is responsible for the formulation, determination and implementation of management policy as it relates to the laboratory's Quality System (QS). Specific responsibilities include but are not limited to; formulation of and implementation of rules, policies and procedures; management of the laboratory's quality system accreditation process (e.g., ISO, etc.); and implementation of industry required system audits and training. This position addresses complex quality issues such as corrective action, proficiency program maintenance, as well as quality control aspects related to testing such as control ranges and trending analysis. It has responsibilities related to training, accreditation, proficiency testing and instrumentation. Additionally this position will be an Administrator of the Laboratory Information System (LIMS), taking an active part in system selection and upgrades, routine maintenance, implementation of quality system aspects and integration with other related software.

This position is responsible for administering a system of objective and subjective measures to evaluate the impact and effectiveness of Bureau programs and activities and to document their performance over time.

This position serves as a project manager for large-scale laboratory projects assigned by the Director; this includes but is not limited to evaluation of current technology systems (e.g. Laboratory Information Management System – LIMS; electronic Quality Management/Reporting Systems, etc.). Projects will vary in scale in terms of performing needs assessment, cost-benefit analyses, and making recommendations to the management team.

TIME % GOALS AND WORKER ACTIVITIES

35% **Goal A: Provision of program, policy and/or procedure analysis and planning for the Bureau. This includes work related to operations, technology (e.g., LIMS), and general program quality management.**

- A1. Routinely meet with supervisor and/or management to identify program areas or policies in need of re-evaluation; participate in prioritization of projects to be completed.
- A2. Develop, implement and oversee a system for measuring, analyzing, and evaluating bureau programs and operations (e.g., LIMS, compliance, lean initiatives, etc.) to improve impact, efficiency, and consistency with Bureau and customer plans and mission.
- A3. Determine study design and methodology to most effectively obtain information relative to the issue or program under study; conduct efficiency and/or effectiveness studies of programs as directed. Ensure a clear understanding of business requirements and project specifications.
- A4. Lead project team selection. Guide team members in preparing timeline estimates including key milestones, etc. Draft project agreement for sign-off by parties involved, identifying areas of responsibility and/or task assignments.
- A5. Research and produce statistics and periodic reports on program activity, trends, and forecasts.
- A6. Assist supervisors and unit staff in SOP development, assessing alternatives in terms of the impact of changes. Discuss and recommend the appropriate alternatives to management.
- A7. Prepare, analyze and report on external and internal auditing.
- A8. Maintain quality related documents and programs either directly or indirectly, i.e. RDA/record retention/change control/ forms/ filing/proficiency
- A9. Evaluate and use LIMS functionality; provide input regarding system use, updates, and/or training needs for staff to improve efficiency, etc. Ensure SOPs are documented for QA purposes.

35% **Goal B: Management of the Quality Assurance Section (QAS)**

- B.1 Manages the laboratory accreditation processes (e.g., ISO, etc.), including but not limited to: preparation, on-going action steps; policy or methodology review, updates, submissions, responses, etc.

- B.2 Monitors system practices to ensure compliance with quality and accreditation standards. Address compliance or quality issues, identifying and implementing corrective actions.'
- B.3 Serve as the primary technical resource on Quality Assurance (QA)/QS related topics, such as control ranges, trending, acceptable validation and verification design, Proficiency Testing programs (internal and external) quality training needs as well as guidance on internal audit processes and external audit standards.
- B.4 Coordinates, trains and participates in internal and external facility audits.
- B.5 Leads, conducts, and/or manages the laboratory's annual quality audit process for each programmatic area; delegate tasks as appropriate and serve as a technical resource to other managers, staff, etc.
- B.6 Define and manage control limits for BLS. Provide guidance to staff in their use and in evaluating results, reports, or corrective action recommendations.
- B.7 Coordinates and reviews all root cause analysis and corrective action processes conducted by the laboratories.
- B.8 Serve as a system administrator, including on LIMS management, to ensure system integrity.
- B.9 Writes and maintains QS documents as well as Installation Qualification/Operational Qualification (IQ/OQ) plans; manages application within the lab.
- B.10 Acts as a change agent, implementing QA/QS program changes as necessary to ensure compliance with evolving accreditation and industry standards.
- B.11 Review performance of Proficiency Testing programs.
- B.12 Oversee calibration program for laboratory equipment e.g. thermometers, hoods, pipettors, centrifuges and others

10% Goal C: Formulation and Implementation of Policy and Procedures, including oversight and evaluation of SOPs developed for specific work units.

- C.1 Leads process of writing, evaluation, and revision of system manuals, technical policies and procedures (Quality Manual, QAS SOP's, etc.).
- C.2 Manages and conducts research and analyses to identify improvements in quality assurance policies, systems and procedures.
- C.3 Provides oversight and works with technical lead staff activities related to system quality issues, e.g. R&D and corrective actions (CAPA).
- C.4 Manages Laboratory information computer system (e.g., LIMS, etc.).
- C.5 Participates on internal/external committees, taskforces, as assigned.

15% Goal D: Administration of assigned laboratory unit operations and staff supervision.

(D1-3 @ 10%)

- D.1 Meet routinely with management team members to discuss quality assurance, audit needs, etc.; provide technical advice and recommendations on long and short term plans related to accreditation standards, review, etc.
- D.2 Direct, supervise, assign and evaluate the activities of assigned staff to ensure accreditation standards, audits, other related quality system plans are maintained and communicated to other laboratory personnel as appropriate.
- D.3 Develop employee objectives, conduct performance evaluations (e.g., PPD), counsel and guide program staff. Monitor the delivery of effective program services, providing training as needed.

- D.4 Review and approve leave schedules, training requests and timesheets. Assure equal access and opportunity for staff to attend training and other career development activities in regards to Affirmative Action and Civil Rights Compliance plans.
- D.7 Manage personnel matters and activities that arise in the work unit, including but not limited to: make recommendations to hire; address performance or discipline issues; monitor the implementation of Affirmative Action/Civil Rights Compliance (AA/CRC) plans within assigned areas of responsibility; etc. Consult with HR staff as needed.

5% Goal E: Responsible for technical expertise and liaison services in support of Bureau initiatives.

- E.1 Keep abreast of scientific findings, methodologies, etc. that impact laboratory operations (e.g., review scientific articles, maintain professional networks, attend seminars, etc.). Discuss relevant topics with management and staff work groups as appropriate to enhance understanding, emerging trends, etc.
- E.2 Serve as a Technical Consultant of the Bureau of Laboratory Services with clients and auditors.
- E.3 Represent the Bureau at meetings with the public, industry, and governmental agencies as requested.
- E.4 Write comprehensive, legible reports of work performed and results obtained.
- E.6 Appear as an expert witness in court to support litigation resulting from data obtained by sample analysis or on related laboratory quality systems.

KNOWLEDGE, SKILLS AND ABILITIES

1. Knowledge and experience in an area of science that would normally be attained through secondary education in quality, statistics, microbiology/chemistry, or comparable combination of training and experience.
2. Knowledge or experience with ISO Laboratory (ISO 17025) accreditation requirements, audits, and compliance activities.
3. Knowledge of program and change management theories.
4. Extensive knowledge of and ability to apply scientific laboratory quality assurance/quality system functions (e.g. QA, Training, Computer software, etc.).
5. Knowledge of personnel management and supervisory techniques.
6. Knowledge of program planning as well as the ability and skill to evaluate the effectiveness and efficiency of unit programs. This includes assessment of resource allocation, workload planning, etc.
7. Working knowledge of, ability to use, efficiently program, and extract and manipulate data from a Laboratory Information Management Systems (LIMS).
8. Working knowledge of computer software (e.g., word processing, databases, and spreadsheets).
9. Ability to evaluate and communicate the performance of laboratory staff.
10. Knowledge and ability to develop and implement policies, rules and regulations.
11. Ability to work effectively independently, as member of a team, or as a leader to achieve goals.
12. Ability to independently and critically observe processes, recording accurate information, come to valid conclusions and present outcomes in a professional manner to applicable staff.
13. Ability to communicate effectively both orally and in writing.
14. Ability to develop effective working relationships with internal and external laboratory customers.
15. Effective time management and organizational skills; this includes the ability to work independently to complete assigned work.

16. Ability to clearly present scientific data when acting as an expert witness or in communicating with peers or subordinates.
17. Working knowledge of statistical parameters, techniques, and procedures and their relationship to laboratory analyses - this includes, but is not limited to: control limits, trending, R&D, validation, and verification
18. Effective data management and record keeping skills, including electronic records.
19. Knowledge/experience with GHS labeling and lab safety protocols.
20. Knowledge of applicable federal statutory and regulatory requirements for laboratories such as USDA, FDA, EPA, ISO and other national regulatory organizations related to agriculture testing pertaining to, but not limited to products such as; food, dairy, animal feed, hemp, pesticides, fertilizers, groundwater, etc.
21. Working knowledge of laboratory operation.

Special Requirements/Work Environment:

1. Ability to work in a laboratory environment with a range of chemicals, reagents, live cultures, etc. which may necessitate the use of personal protective equipment.
2. Some travel may be required (e.g., conferences, meetings).